DEPARTMENT OF HEALTH & HUMAN SERVICES

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CERTIFIED MAIL
RETRUN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2001-DT-11

March 5, 2001

Joel P. Kimelman, D.O.
Supervisory Radiologist
Oakland Imaging Diagnostic Center
27483 Dequindre, Suite 101
Madison Heights, MI 48071

Dear Dr. Kimelman:

We are writing you because on February 15, 2001, your facility was inspected by a representative of the State of Michigan acting in behalf of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following Level 1 finding at your facility:

1. The phantom image score (using an FDA-approved mammography phantom) was found to be less than two (2) masses for your [redacted] mammography machine.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represent a violation of law which may result in FDA taking regulatory action without further

notice to you. These actions include, but are not limited to placing your facility under a Directed Plan of Correction, charging your facility for the cost of onsite monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, the following Level 2 findings were also listed on the inspection report provided at the close of the inspection:

1. Corrective action before further exams for a phantom image with a failing image score or a phantom background optical density, or density difference outside of allowable regulatory limits was not documented.

2. A review of [redacted] random medical reports revealed that [redacted] reports did not contain an assessment category as required by the Quality Standard.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct the Level 1 and Level 2 violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

In addition, we have discussed these findings from your MQSA inspection with your accreditation body, the American College of Radiology (ACR). After an assessment of the serious problems currently present at your facility, we have determined that the quality of mammography may have been severely affected by these conditions. Therefore, we request that you undergo a Targeted Film Check (TFC) by the ACR. This review is an abbreviated version of an Additional Mammography Review (AMR). We have enclosed information pertaining to AMR's required under the MQSA. We believe that this should extend back to 1/31/2001, since that is the date when your consulting medical physicist reported an acceptable phantom image.

Since we have discussed your facility problems with the ACR, they are aware of our request that you undergo a TFC. Your facility is responsible for payment of the costs to the accreditation body for the TFC and that the accreditation body may require a portion or all of this payment prior to the start of the TFC. You should contact the following individual regarding the TFC at your facility.

Priscilla F. Butler, M.S., FAAPM, FACR
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091

Once the TFC has been completed, the ACR will submit a detailed report to the FDA regarding the review and we will provide you with a copy at that time. This report would usually include the total examinations with films showing image quality problems that may need to be repeated, and an overall assessment by the reviewing physician(s) of the quality of mammography from January 31, 2001 to February 15, 2001.

If the TFC indicates that clinical image problems exist that represent a risk to human health, FDA will require you to undergo a more extensive Additional Mammography Review (AMR) or we may request that your notify patients and physicians. This AMR will require you to submit an additional 30 clinical images to the ACR for evaluation.

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207-3179

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

John P. Dempster

for Raymond V. Mlecko
District Director
Detroit District

Enclosures: a/s